

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action mailed April 28, 2009. Currently, claims 1-4, 6-28, 30-38, 43, 50-59, 61-63, 65, 66, 69-76, and 78-87 remain pending of which claims 7, 8, 14, 17-23, 26, 27, 33, 43, 51, 53, 55, 58, 59, 62, 65, 66, 69, 70, 75, 76, 78, and 79 were previously withdrawn from consideration. Claims 1-4, 6, 9-13, 15, 16, 24, 25, 28, 30-32, 34-38, 50, 52, 54, 56, 57, 61, 63, 71-74, and 80-87 have been rejected. In this amendment, claims 51-59, 61-63, and 65-66 have been amended and claims 6 and 25 have been canceled. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 112

In paragraph 4 of the Office Action, claim 6 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. In particular, the Office Action indicated that no disclosure can be found for Applicants' elected species that incorporates both a circumferential band and a longitudinal strip in the active region. Without conceding the correctness of the rejection and in the interest of further prosecution in this case, claim 6 has been canceled. Withdrawal of the rejection is respectfully requested.

In paragraph 6 of the Office Action, claims 52, 54, 56, 57, 61, and 63 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Action indicated that there is insufficient antecedent basis for "the medical device". In response, Applicants have amended "the medical device" of claims 51-59, 61-63, and 65-66 to "the balloon catheter". As such, claims 52, 54, 56, 57, 61, and 63 are believed to have proper antecedent basis. Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC § 103

In paragraph 8 of the Office Action, claims 1-4, 6, 9-13, 15-16, 24-25, 28, 30-32, 34-38, 50, 52, 54, 56-57, 61, 63, 71-74, and 80-86 were rejected under 35 U.S.C. 103(a) as being unpatentable over Masada (U.S. Patent No. 6,514,237) in view of Couvillon (U.S. Publication No. 2003/0236531). After careful review, Applicants respectfully traverse this rejection.

Turing to claim 1, which recites:

1. (Previously Presented) A medical device comprising (a) an

elongate body adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis; and (b) an active region comprising a conductive polymer disposed over the elongate body such that the medical device is expanded in at least one radial dimension relative to said axis upon volumetric expansion of the conductive polymer within the active region; wherein said active region surrounds said elongate body in the form of a continuous circumferential band.

Nothing in Maseda or Couvillon, either taken alone or in combination, appear to disclose many elements of claim 1, including for example, “an active region comprising a conductive polymer disposed over the elongate body such that the medical device is expanded in at least one radial dimension relative to said axis upon volumetric expansion of the conductive polymer within the active region; wherein said active region surrounds said elongate body in the form of a continuous circumferential band”.

The Office Action appears to turn to Couvillon as teaching “wherein said active region surrounds said elongate body in the form of a continuous circumferential band”. This is not understood. Figures 2A-B of Couvillon (relied on by the Office Action) appear to disclose a capture device including aperture 103 and one or more electroactive polymer actuators 110 that open and close the aperture 103 based on control signals sent from a control unit. The one or more electroactive polymer actuators 110 appear to be wrapped around the tubular structural element 102 so that they extend from one side of the aperture 103, around the tubular structural element 102, to the opposite side of the aperture 103. As such, the electroactive polymer actuators 110 of Couvillon clearly do not form a continuous circumferential band.

Further, the Office Action asserts that Maseda discloses “the circumferential band of composite strands expands and functions like a balloon”, which citing column 6, lines 47-59. Column 47-59 of Maseda recites:

However, when a predetermined voltage is applied to the composite strips 500 in a controlled manner, via the control module 300, the composite strips 500, which are constrained from movement on their ends, expand like a balloon as illustrated in FIG. 5A. Because the level of activation for each strip 500 may be independently controlled, the size and shape of the balloon may be varied. For example, non-symmetrical or asymmetrical pressure may be applied by varying the degree of activation for one or more of the composite strips 500. This type of composite strand configuration may be placed at any location in the outer tubular body 114 and may be used any number of times to expand difficult-to-pass passageways.

As can be seen, nothing in this passage appears to disclose “wherein said active region surrounds said elongate body in the form of a continuous circumferential band”. Notably, as shown in Figure 5A, composite strips 500 appear to be oriented longitudinally along the length of the tubular body 114. Hence, nothing in this passage or any other passage of Maseda appears to disclose “wherein said active region surrounds said elongate body in the form of a continuous circumferential band”.

However, the Office Action continues to assert that it would be obvious to one of ordinary skill in the art, in view of the teachings of Couvillon and the suggestions of Maseda, to expand the balloon of Maseda using strips in the circumferential configuration of Couvillon (though not interrupted by an aperture). Applicants respectfully disagree. As understood from the Supreme Court’s decision under *KSR*, there must be some reason to make the claimed combination. MPEP § 2141 states:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

(Emphasis added). The Office Action has failed to provide any reason for providing an active region that surrounds an elongate body in the form of a continuous circumferential band, as neither Maseda nor Couvillon appear to disclose such an element. Instead, the Office Action merely states “it would be obvious to one of ordinary skill in the art, in view of the teachings of Couvillon and the suggestions of Maseda, to expand the balloon of Maseda using strips in the circumferential configuration of Couvillon (though not interrupted by an aperture)”. Nothing in this statement appears to provide the required articulated reasoning with rational underpinning to support the legal conclusion of obviousness, as required by *KSR*. Instead, this statement appears to be merely conclusory. In fact, the only motivation or reason for combining and modifying the teachings of Couvillon and Maseda in the manner suggested by the Office Action appears to come from Applicants’ own specification, which is clearly improper.

Therefore, for at least these reasons, claim 1 is believed to be patentable over Maseda and Couvillon. For similar reasons and others, claims 2-4, 9-13, 15-16, 24, 71-74, and 80-84, which

depend from claim 1 and include additional limitations, are believed to be patentable over Maseda and Couvillon.

Applicants respectfully request that if the rejection is to be maintained, the next Office Action point out with particularity where Maseda or Couvillon disclose "said active region surrounds said elongate body in the form of a continuous circumferential band".

Turning to claim 28, which recites:

28. (Previously Presented) A medical device comprising (a) an elongate body adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis; (b) a balloon; and (c) an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region.

Nowhere does Couvillon or Maseda appear to disclose many of the elements of claim 28, including for example, "an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region".

Maseda appears to disclose incorporating an EAP material (e.g. composite strands 500) in a balloon catheter to induce movements such as wiggling, slithering, twirling, bending, pulsing, vibrating, rotation, expansion, contraction or elongation. While Maseda does appear to disclose that balloon 118 or other portions of the balloon catheter may include the EAP composite strands, nothing in Maseda appears to disclose providing the composite strands beneath the balloon to selectively expand the balloon. Further, nowhere does Maseda appear to disclose the composite strands being disposed beneath any portion of the catheter. As such, nothing in Maseda appears to disclose "an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region", as recited in claim 28.

As noted above, Figures 2A-B of Couvillon (relied on by the Office Action) appear to disclose a capture device including aperture 103 and one or more electroactive polymer actuators 110 that open and close the aperture 103 based on control signals sent from a control unit. The one or more electroactive polymer actuators 110 appear to be wrapped around the tubular

structural element 102 so that they extend from one side of the aperture 103, around the tubular structural element 102, to the opposite side of the aperture 103. Nothing in Couvillon appears to disclose “an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region”, as recited in claim 28.

The Office Action appears to assert that “since Maseda discloses that the strands can be contained within recesses of the outer tube 114 (col. 5, line 61), it would have been obvious to one of ordinary skill in the art to have attached the strands within recesses of tube 116 in order to expand the balloon”. However, nothing in this statement appears to provide a reason to modify the teachings of Maseda or Couvillon to provide “an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region”, as recited in claim 28. As such, the Office Action appears to fail to provide the required articulated reasoning with rational underpinning to support the legal conclusion of obviousness, as required by *KSR*.

Applicants further note that the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, quoting *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006), stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

(see page 14 of the April 30, 2007 decision). It appears that the Office Action has merely found several elements of the claim in the prior art and has made a conclusion of obviousness without any articulated reasoning with some rational underpinning to support the conclusion. Applicants submit that the only motivation or reason for combining Maseda and Couvillon in the manner suggested by the Office Action appears to come from Applicants' own specification, which is clearly improper.

If the Office Action is attempting to assert that “an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially

uninflated state by the volumetric expansion of the conductive polymer within the active region” is somehow an obvious design choice, Applicants respectfully disagree. With regards to obvious design choice, MPEP § 2144.04, Part VI states:

C. Rearrangement of Parts

In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (Claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). However, “The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant’s specification, to make the necessary changes in the reference device.” *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

(Emphasis added). Applicant respectfully asserts that “an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region” is not a mere matter of design choice, but instead, may impact the functionality and/or operation of the device. For example, the claimed balloon may be at least partially expanded by the conductive polymers and the balloon may be at least partially expandable by an inflation media.

Further, as noted above, nowhere does the prior art, namely Maseda or Couvillon, appear to provide any motivation or reason to make the necessary changes to arrive at the claimed device. In fact, the only motivation or reason for combining and modifying the teachings of Couvillon and Maseda in the manner suggested by the Office Action appears to come from Applicants’ own specification, which is clearly improper. Thus, nowhere does the combination of Maseda and Couvillon appear to teach or suggest “an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region”, as recited in claim 28, nor is this element believed to be an obvious design choice.

Therefore, for at least these reasons, claim 28 is believed to be patentable over Maseda

and Couvillon. For similar reasons and others, claims 28, 30-32, 34-38, and 85-86, which depend from claim 28 and include additional limitations, are believed to be patentable over Maseda and Couvillon.

Turning to claim 50, which recites:

50. (Previously Presented) A balloon catheter comprising: (a) an insertable body adapted for insertion into a body lumen of a patient; (b) a device lumen within said insertable body; (c) an inflatable balloon, wherein the interior of said balloon is in fluid communication with said device lumen, and (d) one or more electrically actuated members disposed along at least a portion of the length of said device lumen, said one or more electrically actuated members being adapted to transform at least a portion of the length of said device lumen between (i) a radially expanded state and (ii) a radially contracted state in which said insertable body is more readily inserted into said body lumen of said patient; wherein said one or more electrically actuated member are disposed between the device lumen and the inflatable balloon.

Nothing in Maseda or Couvillon appear to disclose many element of claim 50, including for example, “wherein said one or more electrically actuated member are disposed between the device lumen and the inflatable balloon”. As discussed previously, nothing in Maseda or Couvillon appear to teach or suggest such an element. Therefore, for at least these reasons, claim 50 is believed to be patentable over Maseda and Couvillon. For similar reasons and others, claims 52, 54, 56-57, 61, and 63, which depend from claim 50 and include additional limitations, are believed to be patentable over Maseda and Couvillon.

In paragraph 9 of the Office Action, claim 87 was rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (U.S. Patent No. 6,514,237) in view of Couvillon (U.S. Publication No. 2003/0236531) and further in view of Sharrow (U.S. Patent No. 4,793,359). After careful review, Applicants respectfully traverse this rejection. As discussed previously, claim 28 is believed to be patentable over Maseda and Couvillon and nothing in Sharrow appears to remedy the noted shortcomings. Therefore, for at least these reasons, claim 87 is believed to be patentable over Maseda, Couvillon, and Sharrow.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Further examination and withdrawal of the rejections is respectfully requested.

Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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